Decision Memo for Prothrombin Time and Partial Thromboplastin Time (Revision of ICD-9-CM Codes for Pre-operative Examinations) (CAG-00184N)

Decision Summary

This memorandum serves the purpose of addressing a request for adding codes for pre-operative examinations to the prothrombin time (PT) national coverage determination (NCD) and partial thromboplastin time (PTT) NCD. CMS intends to alter the list of covered diagnoses for partial thromboplastin time and prothrombin time tests by deleting the present line that reads V72.84 (Pre-operative examination, unspecified). We also intend to delete code V72.81 (Pre-operative cardiovascular examination) and V72.83 (Other specified pre-operative examination) from the list of covered codes for PTT.

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Decision Memo

To: Administrative File: CAG-00184N Prothrombin Time (PT) and Partial Thromboplastin Time (PTT) (Revision of ICD-9-CM Codes for Pre-operative Examinations)

From:

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Re: Decision Memorandum for PT and PTT Testing for Pre-operative Examinations

Date: September 29, 2003

Decision

This memorandum serves the purpose of addressing a request for adding codes for pre-operative examinations to the prothrombin time (PT) national coverage determination (NCD) and partial thromboplastin time (PTT) NCD. CMS intends to alter the list of covered diagnoses for partial thromboplastin time and prothrombin time tests by deleting the present line that reads V72.84 (Pre-operative examination, unspecified). We also intend to delete code V72.81 (Pre-operative cardiovascular examination) and V72.83 (Other specified pre-operative examination) from the list of covered codes for PTT.

Background

In accordance with section 4554 of the Balanced Budget Act of 1997, CMS entered into negotiations with the laboratory community regarding coverage and administrative policies for clinical diagnostic laboratory services. As part of these negotiations, the committee utilized evidence-based processes to develop 23 NCDs, which we promulgated through notice and comment. Two of these NCDs were for PT and PTT testing. The rule was proposed in the March 10, 2000 edition of the Federal Register (65 FR 13082) and was made final on November 23, 2001 (66 FR 58788). The final rule called for a 12-month delay in effectuating the NCDs in accordance with the recommendations of the negotiating committee. Thus, the NCDs became effective on November 25, 2002.

In the PT and PTT testing NCDs, CMS determined that coverage of specific PT and PTT tests was reasonable and necessary for certain medical indications. The NCDs contain a narrative describing the indications for which the test is reasonable and necessary. We also developed a list of ICD-9-CM codes that designate diagnoses/conditions that fit within the narrative description of indications that support the medical necessity of the test. This list is entitled "ICD-9-CM codes covered by Medicare," and includes codes where there is a presumption of medical necessity.

In addition, we developed two other ICD-9-CM code lists. The second list is entitled "ICD-9-CM codes denied" and lists diagnosis codes that are never covered by Medicare. The third list is entitled "ICD-9-CM codes that do not support medical necessity" and includes codes that generally are not considered to support a decision that the test is reasonable and necessary, but for which there are limited exceptions. Tests in this third category may be covered when they are accompanied by additional documentation that supports a determination of reasonable and necessary. We determined in these NCDs that any ICD-9-CM code not listed in either of the other ICD-9-CM sections would be categorized into group three.

The PT and PTT testing NCDs include inconsistent information with respect to coverage of pre-operative examinations. The PT NCD includes in the list of covered ICD-9-CM diagnosis codes code V72.84, pre-operative examination, unspecified. The PTT NCD includes in the covered list of ICD-9-CM diagnostic codes code V72.81 (Pre-operative cardiovascular examination,) code V72.83 (Other specified pre-operative examination,) and code V72.84 (Pre-operative examination, unspecified).

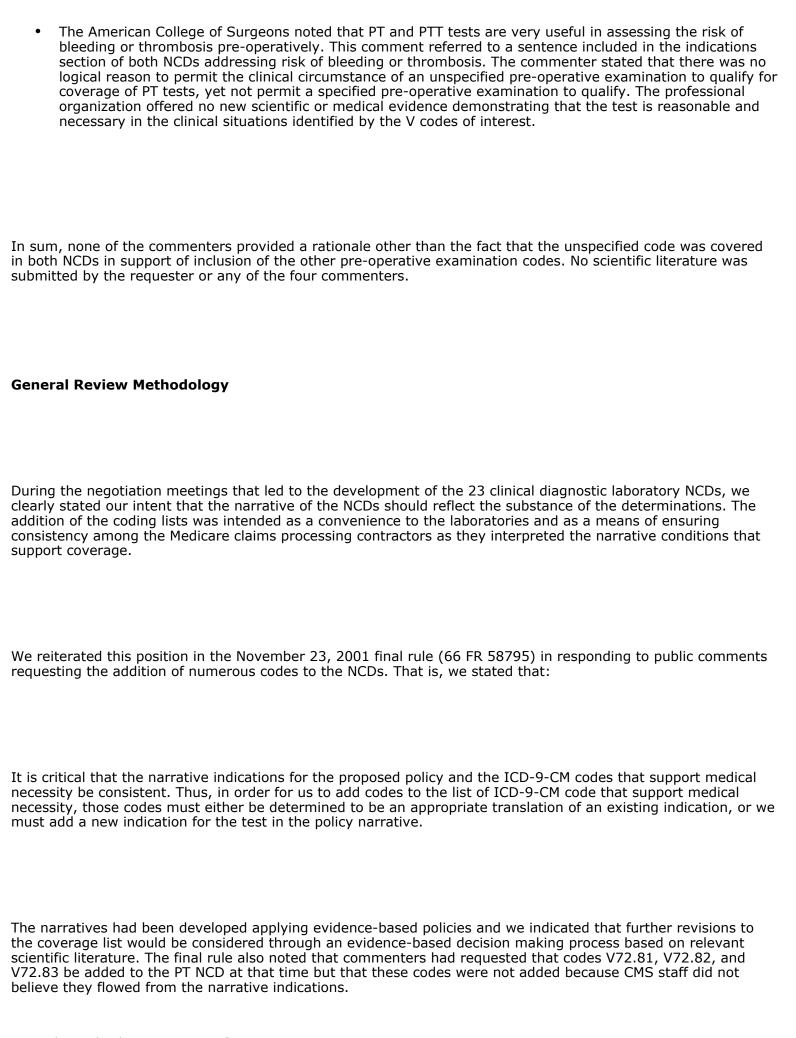
Procedural Background and Scope of Reconsideration

On February 10, 2003 CMS received a letter from Affiliated Healthcare Systems to reconsider the NCD for PT testing to add ICD-9-CM codes V72.81 (Pre-operative cardiovascular examination), V72.82 (Pre-operative respiratory examination), and V72.83 (Other specified pre-operative examination) to the list of covered diagnoses. The basis for the request was that these additional codes were pre-operative codes similar in nature to ICD-9-CM codes listed as covered for each test. ICD-9-CM code V72.84 (Pre-operative examination, unspecified) was listed as a covered code in the NCD for the PT test and ICD-9-CM codes V72.81 (Pre-operative cardiovascular examination,) V72.83 (other specified pre-operative examination) and V72.84 were listed as covered codes in the NCD for the PTT test. The requestor sought consistent covered status in both NCDs for all pre-operative codes. Because the requestor sought consistent treatment of all pre-operative codes, we included in our reconsideration the entire series of pre-operative codes. We posted an announcement of such reconsideration on our coverage website on February 27, 2003. We invited public comment through March 27, 2003. We received four comments summarized as follows.

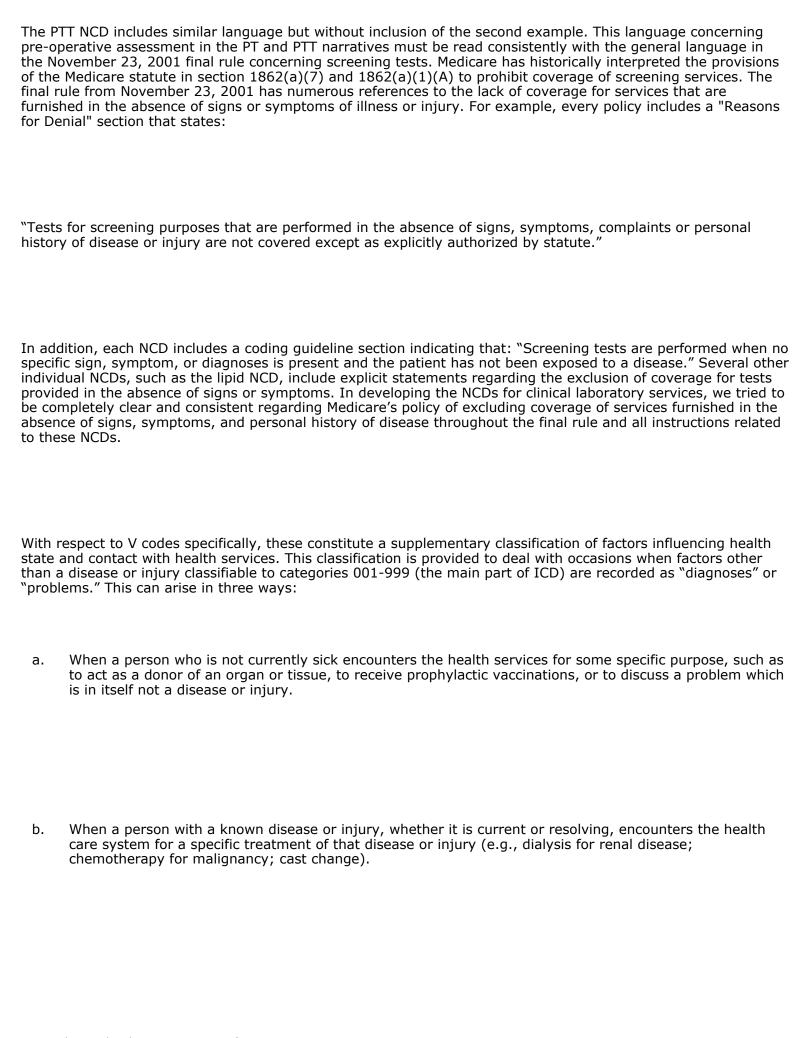
• An individual wrote noting her agreement with adding codes in the V series. But the commenter offered no new scientific or medical evidence demonstrating that the test is reasonable and necessary for those codes.

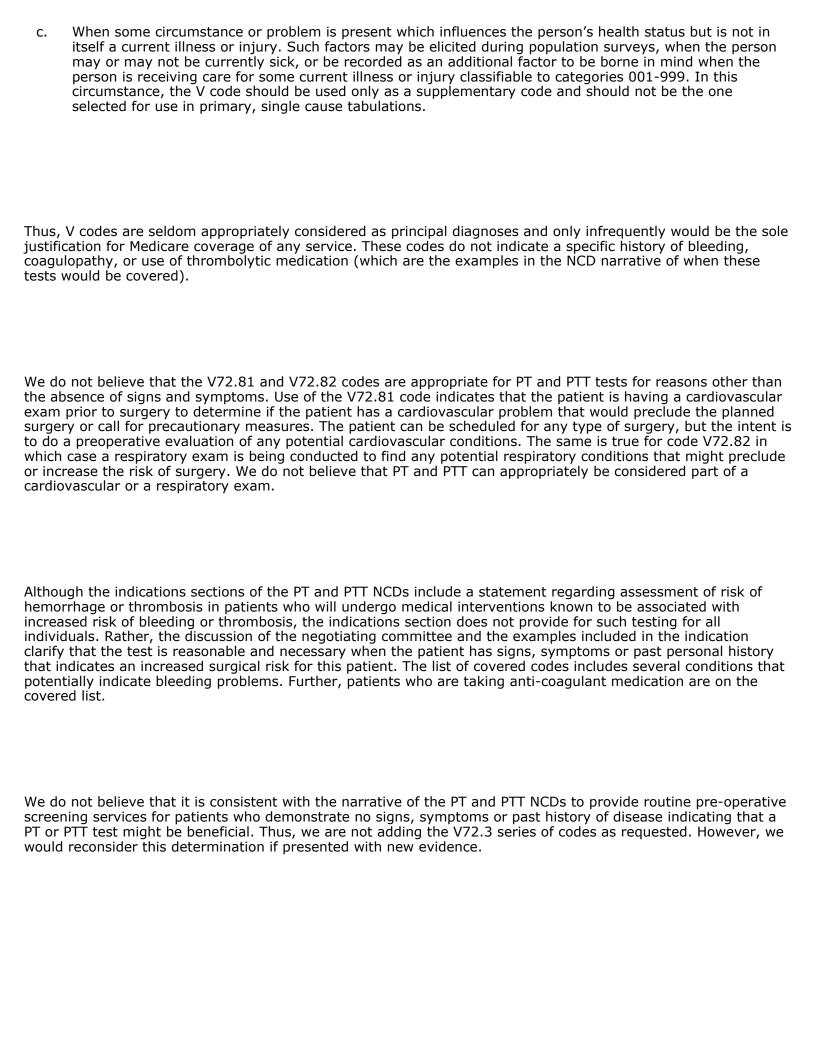
 Another individual wrote stating that she was very much in favor of adding code V72.83 to the NCDs for PT and PTT. The commenter explained that code V72.84 would never be used appropriately for a PT test since the PT test is specified and the V72.84 code is used for unspecified tests. But the commenter offered no new scientific or medical evidence demonstrating that the test is reasonable and necessary for the code proposed.

The College of American Pathology wrote in support of changing the PT and PTT coverage determinations
to add specified V codes to the list of covered diagnoses. But the professional organization offered no new
scientific or medical evidence demonstrating that the test is reasonable and necessary in those
circumstances.



Further, in Program Memorandum AB 02-110 we stated our intent as follows:
The codes included in the NCDs are intended to flow exclusively from the narrative of the NCDs. Therefore, requests for the addition of primary diagnosis codes must include rationale demonstrating the provision of the narrative that supports the inclusion of the code or scientific evidence supporting the inclusion of the condition to the narrative portion of the NCD.
CMS Analysis
Because no new scientific or medical evidence was provided by either the requestor or commenters, consistent with the review methodology set forth in the final rule and summarized in the section above, the purpose of the reconsideration is to determine whether coverage of the codes in question is consistent with the narrative of the NCDs that was developed using evidence-based policies in the negotiated rulemaking process and published on November 23, 2001.
In the PT and PTT NCD narratives, there is an expressed discussion of pre-operative assessment in the indications sections. Specifically, the PT NCD states the following:
"A PT may be used to assess the risk of hemorrhage or thrombosis in patients who are going to have a medical intervention known to be associated with increased risk of bleeding or thrombosis. For example:
 Evaluation prior to invasive procedures or operations of patients with personal history of bleeding or a condition associated with coagulopathy. Prior to the use of thrombolytic medication."





We do agree with the concern of the requestor and commenters that it appears inconsistent to have code V72.84 (Unspecified pre-operative examination) included on the list of covered diagnoses for PT and PTT and to have codes V72.81 (Pre-operative cardiovascular examination) and V72.83 (Other specified pre-operative examination) in the list of covered diagnoses for PTT. The Committee developed these lists of codes with very little time for study and careful evaluation. The Committee was concerned with the possibility of errors in the NCDs and encouraged commenters to submit copies of medical literature supporting their recommendations for change (65 FR 13087).

We agree with the observation that use of code V72.84 (Unspecified pre-operative examination) is not technically appropriate for PT nor is it appropriate for PTT since both are specific tests to assess coagulation status. In addition, we do not believe that these or the other pre-operative codes in question appropriately flow from the narrative when taken in the context of the committee's discussion and the general prohibition on screening services discussed throughout the final rule. Thus, we intend to remove these codes from the lists in both NCDs, as we do not believe they appropriately flow from the indications contained in the NCDs.

We have noted that code V72.84 (Unspecified pre-operative examination) is contained in the urine culture and serum iron studies NCDs. Accordingly, we intend to initiate the process to reconsider these NCDs as well.

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